

JUN 28 2002

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Microlife Corporation
9F, 431 Rui Guang Road
Nei Hu,
Taipei 114
Taiwan, Republic of China

Date Summary Prepared:

April 22, 2002

2. Name of the Device:

Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1-5, with Optional Thermal Printer, Model PR 1KA1

3. Information for the 510(k) Cleared Device (Predicate Device):

The Microlife Wrist Watch Blood Pressure Monitor BP-3BU1-5 is substantially equivalent to the Microlife Automatic Wrist Watch Blood Pressure Monitor, Model BP-3BU1 and Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP-3BTO-1, with Optional Thermal Printer, Model PR1KA1.

4. Device Description:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1-5 is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronics capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the "oscillometric method".

5. **Intended Use:**

The Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1-5 is a device intended to measure the systolic blood pressure and pulse rate of an adult individual by using a non-invasive techniques in which an inflatable cuff is wrapped around the wrist. This device can be used in connection with the Microlife Thermal Printer, Model PR1KA1.

6. **Comparison to the 510(k) Cleared Device (Predicate Device):**

The new model BP-3BU1-5 has the same intended use and is similar in design to the 510(k) cleared device.

The Model BP-1BU1 and the Model BP-3BU1-5 are identical in functionality and performance with the only differences being the additional features such as a printer port function a wider cuff, selection between single or 3 repeated measurement mode with subsequent average calculation of these 3 continuous measurements, and a last measurement recall of 30 sets. The modifications to our original 510(k) cleared device, model BP-3BU1, include ergonomics of the user interface, dimensional specifications and environmental specifications. The temperature measurements algorithm and its software codes of the modified devices remains unchanged. The fundamental scientific technology of the modified device remains the same as that of the 510(k) cleared device.

The average calculation of 3 readings works as follows:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1-5 contains a switchable Average Mode feature in which the device automatically repeats 3 individual measurements cycles, each with a rest time of 45 seconds in between. After that the average of these 3 individual measurements is calculated and shown on the display, together with an average indicator. By certain key operation the user is anytime able to access the individual results of the e measurements.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1-5 in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", CDRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

Testing Conducted Included:

- a. General Functions Testing
- b. Reliability Testing
- c. Drop Test Report (Functional/Mechanical)
- d. Operation Condition Test Report
- e. Storage Test Report
- f. Vibration Test Report (Functional/Mechanical)
- g. Life Test
- h. EMC Test Report (Including EMI/ESD/RS Test Reports)
- i. Other Test Reports
- j. Pulse Rate Accuracy Test Report
- k. Printer Port Function Test
- l. Altitude Test Report

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Microlife Wrist Watch Blood Pressure Monitors, Model BP-3BU1-5 tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

ANSI/AAMI "National Standard for Electronic or Automated Sphygmomanometers" was performed on our predicate device. All relevant sections were addressed and testing conducted. The BP-BU1 met all relevant requirements of this standard, as applicable to our modified device. Repeat testing was not performed for the modified device, as clinical testing results were not affected by the changes to the modified device.

9. Conclusions:

We have demonstrated that the Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1-5 with Optional Thermal Printer, Model PR 1KA1, is as safe and effective as our predicate, the Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1 based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and our "Risk Analysis".



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2002

MicroLife Corporation
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K021305

Trade Name: Wrist Watch Blood Pressure Monitor Model BP-3BU1-5 with
Thermal Printer Model PR 1KA1

Regulation Number: 21 CFR 870.1130

Regulation Name: Non-Invasive Blood Pressure Measurement System

Regulatory Class: Class II (two)

Product Code: DXN

Dated: June 4, 2002

Received: June 6, 2002

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

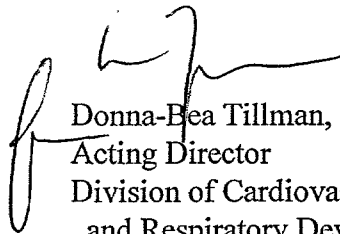
Page 2 - Ms. Susan D. Goldstein-Falk

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman", is written over the typed name and title.

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021305

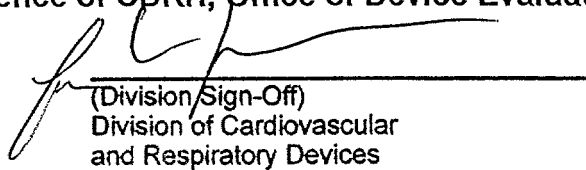
Device Name: Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1-5, with Optional Thermal Printer, Model PR 1KA1

Indications For Use:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP-3BU1-5 is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. This device can be used in connection with the Microlife Thermal Printer, Model PR 1KA1.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K021305

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)